

agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### 2005 Food Safety Survey

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct a consumer survey about food safety under this authority. The food safety survey will provide information about consumers' food safety awareness, knowledge, concerns, and practices. A nationally representative sample of 4,000 adults in households with telephones will be selected at random and interviewed by telephone. This survey will include an oversample of Hispanics with a minimum of 500 Hispanics sampled. Additionally, 200 initial nonrespondents will be asked to participate in a short version of the survey to conduct a nonresponse analysis. Participation will be voluntary. Detailed information will be obtained about food safety risk perception, perceived sources of food contamination, knowledge of particular

microorganisms, food handling practices, consumption of raw foods from animals, and perceived foodborne illness and food allergy experience.

The majority of the questions to be asked are identical to ones asked in the 2001 Food Safety Survey (the 2001 survey). Because of recent national consumer education campaigns about food safety and the large amount of media attention to food safety issues in the past few years, consumer attitudes, knowledge, and practices are likely to have changed greatly since the 2001 survey. FDA needs current information to support consumer education programs and regulatory development. Additionally, this data will be used to measure changes in food safety handling practices and food allergy reactions as part of the Healthy People 2010 food safety objectives and allergen goals. New areas on the survey include awareness of bovine spongiform encephalopathy and acrylamide, refrigeration practices, and updated questions on washing practices for fresh fruits and vegetables.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10,000—Screener	1	10,000	.0167	167
4,000—Survey	1	4,000	.3	1,200
200—Short survey of "initial non-responders"	1	200	.10	20
Total	1	14,200	.4167	1,387

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate is based on FDA's experience with the 2001 survey mentioned previously in this document.

Dated: November 26, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002N-0291]

### Baldev Raj Bhutani; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying Baldev Raj Bhutani's request for a hearing and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debaring Baldev Raj Bhutani from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Bhutani was convicted of a felony under Federal law for conduct related to the regulation of a drug product under the act. Mr. Bhutani has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

**DATES:** This order is effective December 2, 2004.

**ADDRESSES:** Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** S. Mitchell Weitzman, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

On February 12, 1996, Mr. Bhutani, former President and Treasurer of Alra Laboratories, Inc. (Alra), was found

guilty of one count of conspiracy, a Federal felony offense under 18 U.S.C. 371, and six other counts, also Federal felonies, related to violations under sections 301(a), (e), and (k) and 303 of the act (21 U.S.C. 331(a), (e), and (k) and 333(a)(2)). A new trial was ordered by the U.S. District Court for the Northern District of Illinois-Eastern Division on December 17, 1997. On April 28, 1999, the U.S. Court of Appeals for the Seventh Circuit reversed the District Court's ruling that Mr. Bhutani was entitled to a new trial and reinstated his convictions. On October 12, 1999, Mr. Bhutani pled guilty to one count of wire fraud, a Federal felony under 18 U.S.C. 1343. On February 15, 2000, Mr. Bhutani was adjudged guilty of all of these offenses and sentenced by the U.S. District Court for the Northern District of Illinois-Eastern Division. The U.S. Court of Appeals for the Seventh Circuit affirmed the District Court's denial of a motion for a new trial on September 12, 2001.

The basis for these convictions were Mr. Bhutani's violations of various sections of the act involving the drug products LACTULOSE Syrup and K+10 (potassium chloride extended-release tablets). Specifically, Mr. Bhutani, the President and Treasurer of Alra, was convicted of the following:

- Conspiracy (in violation of 18 U.S.C. 371) to commit the following offenses against the United States: (1) Manufacturing and introducing adulterated and misbranded generic drug products into interstate commerce (in violation of 21 U.S.C. 331(a)); (2) failing to establish and maintain records as required under the act (in violation of 21 U.S.C. 331(e)); (3) making false statements to FDA (in violation of 18 U.S.C. 1001); (4) obstructing the administration of law in proceedings pending before FDA (in violation of 18 U.S.C. 1505); and (5) obstructing proceedings before a Federal grand jury (in violation of 18 U.S.C. 1503).

- Adulterating the drug product LACTULOSE Syrup, United States Pharmacopeia (USP), lot 52-230-P, in violation of 21 U.S.C. 331(k), by including decomposed LACTULOSE raw material in the finished drug product, and by deviating from the approved manufacturing procedures by adding an undocumented substance, sodium hydroxide, to this drug product in an unapproved manner.

- Failing to establish and maintain records as required under the act (in violation of 21 U.S.C. 331(e)), specifically failing to establish and maintain accurate drug manufacturing batch production records for the drug product LACTULOSE Syrup, USP, lot

52-230-P, in that he failed to document the unauthorized addition of sodium hydroxide more than 2 years after the original manufacture of this lot.

- Introducing into interstate commerce, in violation of 21 U.S.C. 331(a), the drug product LACTULOSE Syrup, USP, lot 52-230-P, which (1) was not manufactured in accordance with current good manufacturing practice regulations and (2) contained an undocumented substance, sodium hydroxide.

- Adulterating the drug product LACTULOSE Syrup, USP, lot 92-558-P, by violating current good manufacturing practice regulations and by preparing and holding the drug product under unsanitary conditions whereby it may have been contaminated with filth (21 U.S.C. 331(k)). Specifically, Mr. Bhutani received the drug product's active raw material, LACTULOSE concentrate, in punctured drums and then directed Alra employees to inject hot glue into the punctures to plug the leaks, and to wrap self-adhesive duct tape over the punctures, and thereafter used this contaminated raw material in the manufacture of a finished drug product.

- Introducing into interstate commerce the drug product LACTULOSE, lot 92-558-P, which was adulterated in that it was not manufactured in accordance with current good manufacturing practice regulations, and it was prepared and held under unsanitary conditions whereby it may have been contaminated with filth, in violation of 21 U.S.C. 331(a). Alra then used this contaminated raw material in the manufacture of a finished drug product and shipped it in interstate commerce to customers.

- Adulterating the drug product K+10 by violating current good manufacturing practice regulations under 21 U.S.C. 331(k), by contaminating this drug product with metal shavings from a stainless steel pipe, and by preparing and holding the drug product under unsanitary conditions whereby it may have been contaminated with filth and rendered injurious to health. Specifically, Mr. Bhutani directed employees to make tablets from the drug product when he knew the granulation powder contained metal fragments from a stainless steel pipe.

As a result of Mr. Bhutani's convictions and because he was convicted of felonies that were clearly related to the regulation of a drug product under the act, FDA served him by certified letter on February 6, 2003, a proposal to permanently debar him from providing services in any capacity to a person that has an approved or

pending drug product application. The proposal also offered Mr. Bhutani an opportunity for a hearing on the proposal. FDA based the debarment proposal on a finding that Mr. Bhutani was convicted of a felony under Federal law for conduct relating to the regulation of Alra's drug products.

The certified letter informed Mr. Bhutani that his request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Mr. Bhutani that the only material issue of fact was whether he was convicted as alleged in the letter. Finally, the letter informed Mr. Bhutani that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated January 30, 2003,<sup>1</sup> Mr. Bhutani requested a hearing on the proposal and attached supporting materials. In his request for a hearing, Mr. Bhutani acknowledges his convictions under Federal law as alleged by FDA. However, he disputes many of the facts and judicial decisions that formed the basis for his convictions.

We reviewed these materials, as well as supplementary submissions from Mr. Bhutani dated February 25, 2003, March 17, 2003, February 17, 2004, and November 12, 2004, and find that they do not create a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact. Hearings will be granted neither on issues of policy or law or on mere allegations, denials, or general descriptions of positions and contentions, nor on data and information insufficient to justify the factual determination urged. (See 21 CFR 12.24(b).)

The Associate Commissioner for Regulatory Affairs has considered Mr. Bhutani's arguments and concludes that they are unpersuasive and fail to raise

<sup>1</sup> Mr. Bhutani's response pre-dated his actual receipt of the certified letter. This was because service was initially attempted at his home instead of at the prison at which he was incarcerated. We presume that Mr. Bhutani was informed of this attempted service and preemptively submitted his request for a hearing. A second attempt at service at the prison facility at which he is incarcerated was successful. In any event, the delivery dates do not alter the nature of Mr. Bhutani's request for a hearing or our application of summary judgment in this matter.

a genuine and substantial issue of fact requiring a hearing.

## II. Legal Arguments Raised by Mr. Bhutani

Mr. Bhutani raised a number of legal arguments in support of his hearing request. These legal arguments are not relevant to the decision to grant a hearing because Mr. Bhutani has not raised a genuine and substantial issue of fact. A hearing will not be granted on issues of law. See 21 CFR 12.24(b)(1). Mr. Bhutani's legal arguments are discussed in the following paragraphs.

### A. Materiality as an Element of "Intent to Defraud"

Mr. Bhutani contends that "materiality" as an element of "intent to defraud" was erroneously not given as a jury instruction, citing *U.S. v. Neder*, 527 U.S. 1 (1999). *Neder* held that when Congress used the term "to defraud" in the mail and wire fraud statutes, Congress incorporated the common law requirement of materiality as an element of the offense.

Mr. Bhutani maintains that the violations cited by the proposal to debar are not material and that there is no evidence that the acts underlying the violations affected the quality, strength, purity, or potency of the drug products under his control.

The act requires FDA to mandatorily debar an individual who has been convicted of certain Federal felonies. Thus, the only relevant factual issue here is whether Mr. Bhutani was, in fact, convicted of a Federal felony for conduct related to the regulation of a drug product, and not whether the acts underlying the violations are material. Accordingly, Mr. Bhutani's argument is without merit.

### B. Ex Post Facto

Mr. Bhutani maintains that in 1988, section 301(e) of the act did not specifically require batch documentation, as it does now, and therefore *ex post facto* principles apply. An *ex post facto* law is one that reaches back to punish acts that occurred before enactment of the law or that adds a new punishment to one that was in effect when the crime was committed. *Ex Parte Garland*, 4 Wall 333, 337, 18L. Ed 366 (1866); *Collins v. Youngblood*, 497 U.S. 37 (1990).

Mr. Bhutani's assertion regarding section 301(e) relates to the facts and findings underlying his conviction. These facts and findings are not relevant to this debarment proceeding. As stated previously in this document, the only relevant consideration under section 306(a)(2) of the act (21 U.S.C. 335a(a)(2))

is whether Mr. Bhutani was convicted of a felony under Federal law for conduct related to the regulation of a drug product under the act. Therefore, Mr. Bhutani's argument regarding section 301(e) and the Ex Post Facto Clause in connection with this debarment proceeding is without merit.

Mr. Bhutani also suggests that, in general, the Ex Post Facto Clause of the U.S. Constitution prohibits application of section 306(a)(2) of the act (21 U.S.C. 335a(a)(2)) to him because this section was not in effect at the time of Mr. Bhutani's criminal conduct.

With the enactment of the Generic Drug Enforcement Act (GDEA) on May 13, 1992, Congress amended the act to include section 306(a)(2) of the act. Mr. Bhutani's implication that application of the mandatory debarment provisions of the act is prohibited by the Ex Post Facto Clause is unpersuasive. Because the intent behind debarment under section 306(a)(2) of the act is remedial rather than punitive, this section does not violate the Ex Post Facto Clause.

The congressional intent with respect to actions under section 306(a)(2) of the act is clearly remedial. Congress created the GDEA in response to findings of fraud and corruption in the generic drug industry. Both the language of the GDEA itself and its legislative history reveal that the purpose of the debarment provisions set forth in the GDEA is "to restore and ensure the integrity of the ANDA [abbreviated new drug application] approval process and to protect the public health." (See section 1, Public Law 102-282, the Generic Drug Enforcement Act of 1992.) This is a remedial rather than punitive goal. In *Bae v. Shalala*, 44 F. 3d 489 (7th Cir. 1995), the Seventh Circuit upheld FDA's debarment under the GDEA of the former president of a generic drug manufacturing firm, based on his antecedent conviction for providing an "unlawful gratuity" to an FDA official. Although Bae argued that his debarment was "retroactive punishment" in violation of the Ex Post Facto Clause of the U.S. Constitution, the Seventh Circuit found that Bae's debarment was remedial, not punitive, and therefore did not violate the Ex Post Facto Clause. (*Bae*, 44 F. 3d at 493, 495-96). The Seventh Circuit recognized that, to achieve its remedial goal of restoring consumer confidence in the generic drug industry, Congress appropriately determined that it could prohibit felons such as Bae from future activity in the industry. (*Id.* at 496.) (See also *DiCola v. FDA*, 77 F. 3d 504 (D.C. Cir. 1996 (debarment of a convicted felon did not violate Ex Post Facto Clause); *Manocchio v. Kusserow*, 961 F. 2d 1539,

1542 (11th Cir. 1992) (exclusion of physician from participation in Medicare programs because of criminal conviction is remedial, not punitive and therefore did not violate the Ex Post Facto Clause).)

The Supreme Court has long held that statutes that deny future privileges to convicted offenders because of their previous criminal activities to insure against corruption in specified areas do not impose penalties for past conduct and, therefore, do not violate the *ex post facto* prohibitions. (See, e.g., *Hawker v. New York*, 170 U.S. 189, 190 (1898) (physician barred from practicing medicine for a prior felony conviction); *De Veau v. Braisted*, 363 U.S. 144 (1960) (convicted felon's exclusion from employment as officer of waterfront union is not a violation of the Ex Post Facto Clause).) In *De Veau*, the court upheld a law that prohibited a convicted felon from employment as an officer in a waterfront union. The purpose of the law was to remedy the past corruption and to insure against future corruption in the waterfront unions. The court in *De Veau*, 363 U.S. at 160, stated:

The question in each case where unpleasant consequences are brought to bear upon an individual for prior conduct, is whether the legislative aim was to punish that individual for past activity, or whether the restriction of the individual comes about as a relevant incident to a regulation of a present situation, such as the proper qualifications for a profession \* \* \*.

As in *De Veau*, the legislative purpose of section 306(a)(2) of the act is to ensure that fraud and corruption are eliminated from the drug industry. The restrictions placed on individuals convicted of a felony under Federal law are not intended as punishment but are "incident to a regulation of a present situation" (*De Veau*, 363 U.S. at 160) and are necessary to remedy the past fraud and corruption in the industry. Because the intent of the GDEA is remedial rather than punitive, Mr. Bhutani's argument that the GDEA violates the Ex Post Facto Clause must fail.

### C. Scope of Debarment Authority

Mr. Bhutani asserts that the proposal to debar him and the debarment provisions themselves (section 306(a)(2)(B) of the act) are too broad and not specific, so he is entitled to a hearing. This argument is without merit.

Neither the proposal to debar nor the act's debarment provisions, on which the proposal to debar was based, are broad or unspecific. The debarment proposal set forth expressly the conduct on which the proposal is based, the findings of FDA, the agency's proposed

action, and the procedure for requesting a hearing. Section 306(a)(2)(B) of the act clearly mandates the debarment of an individual who has been convicted of a Federal felony for conduct relating to the regulation of any drug product. The act defines the conduct and felony conviction that lead to debarment. The period of debarment is also in section 306(c)(2) of the act, which states that the debarment is permanent.

In fact, the debarment provisions are narrowly drawn to accomplish the legitimate government purposes of ensuring the integrity of the drug regulatory process and protecting the public health. The debarment provisions further the compelling governmental interest of "restor[ing] consumer confidence in generic drugs by eradicating the widespread corruption in the generic drug approval process." (*Bae v. Shalala*, 44 F. 3d 489, 493 (7th Cir. 1995).)

#### D. Double Jeopardy

Mr. Bhutani asserts that as he has already been convicted and sentenced for his actions, further punishment in the form of a permanent debarment violates the Double Jeopardy Clause of the Fifth Amendment to the U.S. Constitution. The Double Jeopardy Clause states that no person shall "be subject for the same offense to be twice put in jeopardy of life or limb." Mr. Bhutani relies on *U.S. v. Halper*, 490 U.S. 435 (1989), which held that a civil sanction can constitute a multiple punishment of the sort prohibited by the Double Jeopardy Clause, to argue that permanent debarment is not rationally related to any remedial purpose and is disproportionate to damages resulting from his violative acts.

Mr. Bhutani's arguments are unpersuasive. First, "jeopardy" cannot attach because the effect of section 306(a)(2) of the act is remedial, not punitive. As previously stated, the legislative goal of this section of the act is to restore and ensure the integrity of the drug approval process and to protect the public health by eradicating fraud and corruption from the drug industry. This is plainly a remedial rather than punitive goal.

Second, the Supreme Court in *Hudson v. United States*, 522 U.S. 93 (1997), in large part disavowed the method of analysis used in *Halper* to determine whether a sanction violates the Double Jeopardy Clause. The Court in *Hudson* stated that the Double Jeopardy Clause protects only against the imposition of multiple criminal punishments for the same offense in successive proceedings. (*Hudson*, 522 U.S. at 98-99). It does not prohibit the

imposition of any additional sanction that could, "in common parlance," be described as punishment. (*Id.*) (Internal quotation marks and citations omitted).

The Court added that whether a particular punishment is considered criminal or civil is first a matter of statutory construction. (*Id.*) That is, a court first must ask whether the legislature, "in establishing the penalizing mechanism, indicated either expressly or impliedly a preference for one label or the other." (*Id.* at 99 (quoting *United States v. Ward*, 448 U.S. 242, 248 (1980)).) Moreover, where the legislature has indicated an intention to establish a civil penalty, a court must inquire further whether the statutory scheme is "so punitive either in purpose or effect" as to "transform what was clearly intended as a civil remedy into a criminal penalty." (*Id.* at 99 (quoting *Rex Trailer Co. v. United States*, 350 U.S. 148, 154 (1956)).)

The debarment of Mr. Bhutani is not a criminal penalty under *Hudson*. In enacting the GDEA, Congress clearly intended that debarment serve as a civil penalty. In *Hudson*, the Court found "it significant that the authority to issue debarment orders is conferred [by statute] upon the 'appropriate Federal banking agencies,'" holding "[t]hat such [debarment] authority was conferred upon administrative agencies is prima facie evidence that Congress intended to provide for a civil sanction." (*Id.* at 103 (citations omitted).)

The GDEA explicitly provides FDA with the authority to permanently debar individuals convicted of certain felonies, such as Mr. Bhutani, from "providing services in any capacity to a person that has an approved or pending drug product application" (section 306(a)(2) of the act). Thus, under *Hudson*, the terms of the GDEA are prima facie evidence that Congress intended the debarment provisions to be civil in nature.

Under the second prong of *Hudson*, the debarment authorized by the GDEA is not so punitive either in purpose or effect as to transform this civil remedy into a criminal penalty. In *Hudson*, the Court considered whether a permanent debarment sanction prohibiting participation in any banking activities had such a punitive purpose or effect. The Court concluded that there was no evidence to establish that the debarment sanction at issue was "so punitive in form and effect as to render [it] criminal despite Congress' intent to the contrary." (*Hudson v. United States*, 522 U.S. at 104 (quoting *United States v. Ursery*, 518 U.S. 267, 290 (1996)).) The Court in *Hudson* relied on the analysis of *Kennedy v. Mendoza-*

*Martinez*, 372 U.S. 144, 168-169 (1963), in reaching this holding.

The *Hudson* court further noted that debarment proceedings have not historically been viewed as punishment. (*Hudson*, 522 U.S. at 104). The Court found that "the [debarment] sanctions imposed do not involve an 'affirmative disability or restraint,' as that term is normally understood." (*Id.* (quoting *Flemming v. Nestor*, 363 U.S. 603, 617 (1960)).) The Court also found that the debarment sanction in the banking statute at issue in the *Hudson* case does not "come into play 'only' on a finding of scienter," because willfulness is not a prerequisite to the imposition of the debarment sanction. (*Id.* (quoting *Kennedy*, 372 U.S. at 169).) Likewise, the GDEA does not require a finding of willfulness as a prerequisite to imposing debarment. In addition, the Court explained that the fact that the conduct for which the debarment is imposed may also be criminal is insufficient to render the debarment sanctions criminally punitive. (*Id.*) Finally, and significantly, the Court explained that the general deterrence of the conduct at issue resulting from an individual debarment is insufficient to render the debarment criminal. (*Id.*) These factors apply as much to debarment under the GDEA.

Furthermore, the GDEA's permanent prohibition on services in any capacity to a person with an approved or pending drug product application is not excessive in relation to the statute's remedial purpose. The Supreme Court has upheld similar statutes which, for remedial purposes, impose permanent prohibitions. (See *Hudson v. United States*, 522 U.S. 93 (1997); *Hawker v. New York*, 170 U.S. 189, 190 (1898); *De Veau v. Braisted*, 363 U.S. 144 (1960).)

The preclusion of Mr. Bhutani from providing any type of service to holders of pending or approved drug product applications is not excessive in relation to the remedial goals of the GDEA. The D.C. Circuit has held that the GDEA's prohibition on services in any capacity serves the statute's remedial purpose. (*FDA v. DiCola*, 77 F. 3d 504 (D.C. Cir. 1996).) Congress prohibited all services to avoid the serious administrative difficulties involved in distinguishing between those positions clearly related to drug regulation and those not clearly related. (*Id.* at 507; see also *Siegel v. Lyng*, 851 F. 2d 412, 416 (D.C. Cir. 1988).) Furthermore, the GDEA's prohibition ensures that the purposes underlying the debarment provisions are not circumvented or undermined. (*DiCola*, 77 F. 3d at 507; see also *Farley and Calfee, Inc. v. USDA*, 941 F. 2d 964, 968 (9th Cir. 1991).) Finally, as

previously noted, the Supreme Court in *Hudson* upheld a similar statute that, for remedial purposes, imposes a prohibition on participation in any banking activity. (See also *DiCola*, 77 F. 3d at 506–507 (debarment of a convicted felon does not violate the Double Jeopardy Clause); *Manocchio v. Kusserow*, 961 F. 2d 1539, 1542 (11th Cir. 1992) (exclusion of a physician from the Medicaid program because of a criminal conviction does not violate the Double Jeopardy Clause).)

Under *Hudson*, debarment under the GDEA is not so punitive either in purpose or effect as to render the penalty criminal. Thus, Mr. Bhutani's argument that debarment under the GDEA violates the Double Jeopardy Clause is unpersuasive.

#### E. Waiver of Further Remedial, Civil, or Criminal Actions

Mr. Bhutani maintains that FDA is estopped from seeking to debar him because the agency waived additional remedial, civil, or criminal actions against him by entering into "agreements" with him concerning his cooperation in bringing Alra's operations in compliance with FDA regulations. Mr. Bhutani also asserts that the proposal to debar is punitive rather than remedial. These arguments are also unpersuasive.

As discussed in section II.D of this document, a debarment is a remedial, not punitive, action. Furthermore, Mr. Bhutani's argument that FDA is estopped from pursuing further administrative action by virtue of prior "agreements" is unpersuasive. Mr. Bhutani cites no legal authority, and we are unaware of any such authority, that would bar FDA from pursuing this appropriate remedial action as mandated by the GDEA.

#### F. "Clean Hands" Doctrine

Mr. Bhutani maintains that he and Alra entered into two agreements (a consent agreement and a voluntary agreement) with FDA that he and Alra complied with and that FDA was satisfied with. He asserts that under Congressional pressure, FDA initiated a seizure action and a criminal proceeding against Alra. Mr. Bhutani contends that FDA has acted in bad faith and, under the "clean hands" doctrine, should not be allowed to seek additional remedies and relief. This argument is also without merit.

Under the "clean hands" doctrine, a party seeking a judgment is not entitled to relief in equity if the person has done anything unfair or illegal in relation to the subject of the lawsuit. *Precision Instrument Mfg. Co. v. Automotive*

*Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). FDA has not acted in bad faith with respect to any agreements with Mr. Bhutani or Alra. Furthermore, FDA is not seeking any judgment or relief in equity against Mr. Bhutani. FDA is applying to Mr. Bhutani the statutory requirement regarding mandatory debarment of individuals convicted of a felony under Federal law for conduct related to the regulation of a drug product under the act. Therefore, Mr. Bhutani's argument regarding the "clean hands" doctrine is without merit.

#### G. Estoppel by Laches

Mr. Bhutani maintains that FDA is estopped from taking this regulatory action due to an "unreasonable amount of time that has elapsed." He cites *Costello v. U.S.*, 365 U.S. 265 (1961), in support of his contention. *Costello* involved an individual whose U.S. naturalization was revoked 27 years after his application. The *Costello* case is not in any way relevant or analogous to the circumstances at issue here, but even if it were, the Court's holding that the petitioner's rights were not violated by a 27-year delay in initiating citizenship revocation undermines, as opposed to supports, Mr. Bhutani's argument. The Court cited, as is the case here, the availability of accurate records and documents attesting to the petitioner's misdeeds (*id.* at 282–283).

FDA initiated administrative action to debar Mr. Bhutani in a timely fashion. Section 306(l)(2) of the act provides a 5-year window from the date of conviction for the agency to initiate the debarment process. Mr. Bhutani's conviction was reinstated on April 29, 1999. The agency issued a proposal to debar on February 6, 2003, within the 5-year statutory window. Therefore, Mr. Bhutani's assertion is unpersuasive.

#### H. Other Arguments

Finally, Mr. Bhutani argues that FDA must consider a number of factors in this debarment proceeding, including the nature and seriousness of the offense; management participation in the offense; voluntary steps taken to minimize the impact of the offense on the public; changes in ownership, management, or operations that have corrected the cause of the offense and decreased the likelihood of a recurrence; evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements; and prior convictions. Again, the only relevant fact under section 306(a)(2) of the act is whether Mr. Bhutani was convicted of a felony under Federal law

for conduct related to the regulation of a drug product. Therefore, Mr. Bhutani's argument that FDA must consider other factors is without merit.

#### III. Denial of Hearing

In his requests for a hearing, Mr. Bhutani does not present any information showing there is a genuine and substantial issue of fact requiring a hearing. Mr. Bhutani does not dispute that he pled guilty to one count of wire fraud and that he was found guilty of seven other counts, all felonies under Federal law. Nor does he dispute that he was convicted of felonies that were clearly related to the regulation of a drug product under the act. The facts underlying Mr. Bhutani's convictions have been established by his convictions and, therefore, are not at issue. Thus, FDA finds that Mr. Bhutani has failed to identify any genuine and substantial issue of fact requiring a hearing. In addition, Mr. Bhutani's legal arguments do not create a basis for a hearing and, in any event, are unpersuasive. Accordingly, FDA denies Mr. Bhutani's request for a hearing.

#### IV. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, under section 306(a) of the act and under authority delegated to him, finds that Mr. Baldev Bhutani has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act (Section 306(a)(2)(B)) of the act).

As a result of the foregoing findings, Mr. Baldev Raj Bhutani is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Bhutani in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Bhutani, during the period of his debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any ANDAs submitted by or with the assistance of Mr. Bhutani during the period of his debarment.

We note that Mr. Bhutani has petitioned the U.S. Supreme Court for writ of certiorari of the Seventh Circuit's decision in his case. Should the outcome of further judicial proceeding result in Mr. Bhutani's conviction being reversed, under section 306(d)(3)(B)(i) of the act, the order of debarment will be withdrawn. Mr. Bhutani may file an application to terminate his debarment, under section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 2002N-0291 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(f). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 24, 2004.

**John M. Taylor,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 04-26532 Filed 12-1-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0493]

#### Draft Guidance for Industry on Recommended Approaches to Integration of Genetic Toxicology Study Results; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." This draft guidance is intended to inform industry on how the Center for Drug Evaluation and Research (CDER) views positive findings in genetic toxicology assays, and to provide recommendations to industry on how to proceed in assuring safety of healthy subjects or patients when results in genotoxicity studies suggest a potential cancer or genetic hazard.

**DATES:** Submit written or electronic comments on the draft guidance by

January 31, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** David Jacobson-Kram, Center for Drug Evaluation and Research (HFD-024), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-443-5346.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Recommended Approaches to Integration of Genetic Toxicology Study Results." Risk for carcinogenesis is usually determined in rodent assays, in either 2-year studies or shorter-term studies using alternative models (ICH S1B). Regulatory decisions involving both single- and repeat-dose clinical studies are discussed in this guidance. Pharmaceuticals administered through oral, intravenous, topical, and other routes, as appropriate, are subject to this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommended approaches to integration of genetic toxicology study results. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals

may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-26533 Filed 12-1-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Longitudinal Investigation of Fertility and the Environment

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register**, under the title "Determinants of Male and Female Fecundity and Fertility," on January 9, 2004, page 1589 and allowed 60-days for public comment. Two public comments were received from the American Society for Reproductive Medicine and the American Chemistry Council Phthalate Esters Panel regarding specific aspects of the proposed methodology. Overall, comments from the former group pertained predominantly to clinical issues while the latter group's comments provided their rationale for the omission of phthalates from the protocol. These comments were useful in modifying the proposed study and instruments. The purpose of this notice is to allow an additional 30 days for public comment.

#### 5 CFR 1320.5 (General Requirements) Reporting and Recordkeeping

*Requirements:* Final Rule requires that the agency inform the potential